MAR - 8 2012 K113151

14.0 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

Submitter's name, address, telephone number, contact person, and date summary prepared:

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c. Date of Summary Preparation: March 7, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

Trade/Proprietary Name: iFS Laser System
Common/Usual Name: Laser
Classification Name: Keratome
Classification Code(s): 79 GEX, 86 HNO

IDENTIFICATION OF THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE OR DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:

510(k) #	Trade Name	Manufacturer
K101626	LenSx 550 Laser System	LenSx Lasers
K073404	IntraLase FS Laser	IntraLase Corp.
K863725	Cataract Diamond Knife	Medical Technology Development Corp

A DESCRIPTION OF THE DEVICE THAT IS THE SUBJECT OF THE 510(K), INCLUDING EXPLANATION OF HOW THE DEVICE FUNCTIONS, BASIC SCIENTIFIC CONCEPTS, SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS (DESIGN, MATERIAL, PHYSICAL PROPERTIES):

The iFS Laser System intended use is a precision ophthalmic surgical laser designed for use as an ophthalmic surgical laser. It is indicated for use as follows:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty
- In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions, both penetrating and intrastromal

The iFS Laser System uses focused femtosecond laser pulses to create incisions and separates tissues in the cornea. Corneal dissection with the iFS Laser is achieved through precise individual micro-photodisruptions of tissue, which are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce continuous incisions or tissue separation. These laser pulses are delivered through a disposable applanation lens that contacts the cornea while fixating the eye under low vacuum.

STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE:

The technological characteristics of the iFS Laser System are substantially equivalent to those cleared under K101626 and K073404 for corneal resections and incisions. No new software and/or hardware were required for the additional indication for arcuate incisions for the iFS Laser System.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:

The iFS Laser System has undergone testing and is in compliance with applicable safety standards. The iFS Laser System was able to create arcuate incisions, both penetrating and intrastromal, safely and effectively. Thus, the iFS Laser System and the predicate devices have similar safety, effectiveness and performance profiles.

APPLICABLE STANDARDS (LASER AND PATIENT INTERFACE):

- IEC 60601-1 Medical Electrical Equipment – General Requirements for Safety, 2nd edition, Amendment 2
- IEC 60601-1-2 Medical Electrical Equipment – Electromagnetic Compatibility, 2nd Edition, Amendment 1
- IEC 60601-2-22 Medical Electrical Equipment – Safety of Diagnostic and Therapeutic Laser Equipment, 2nd Edition, Amendment 2

- ISO 10993-10:2002 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type Hypersensitivity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 – Tests for In Vitro Cytotoxicity
- AAMI 11137-1:2006/(R) 2010 Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development
- AAMI 11137-2:2006/(R) 2010 Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose

PATTERN FIDELITY TESTING:

Data were collected from the iFS Laser System to measure depth pattern fidelity for arcuate incisions at the 95% confidence interval. All results met the 95% confidence acceptance criteria. Data were additionally collected from the iFS Laser System to measure pattern fidelity for position, angle and diameter for arcuate incisions at the 95% confidence interval. All results met the 95% confidence acceptance criteria.

HUMAN CADAVER EYE TESTING:

An AMO directed study was executed to determine the effectiveness of laser parameters in the creation of arcuate incisions in the human cadaver eye model. The iFS Laser System was used to cut intrastromal and penetrating arcuate incisions in the human cornea. For comparison, a standard radial keratotomy diamond blade was used to create penetrating incisions. Results of the study indicate that the iFS Laser System can create single or paired arcuate incisions. With appropriate depth in glass settings, the intrastromal incision can be created without risking perforation of either corneal surface.

ANIMAL TESTING:

AMO conducted a series of studies in rabbits to evaluate the safety of penetrating and intrastromal incisions. The first studies assessed the initial safety of the intrastromal arcuate incisions. Subsequent studies, including a GLP rabbit study, were performed to demonstrate safety of penetrating and intrastromal arcuate incisions when performed by the iFS Laser System. The GLP study conclusively demonstrates the safety of arcuate incisions in the cornea, both penetrating and intrastromal, when performed by the iFS Laser System.

CLINICAL TRIAL RESULTS:

A clinical trial assessed the iFS Laser System for demonstration of safety of the intrastromal arcuate incisions in the cornea. A total of 21 subjects were enrolled at one investigative site in a non-randomized, two-arm study design based on cataract status.

No eyes in this study with a BSCVA of 20/20 or better at baseline had a post-operative BSCVA of worse than 20/40. No eyes in this study had induced manifest refractive astigmatism of greater than 2.00 diopters. No eyes experienced an adverse event.

Endothelial cell counts (central and two peripheral endothelium locations) were compared between the study and non-study fellow eyes. No statistically significant differences were observed.

Ophthalmic symptoms such as glare, haze, halos, clarity, dry eye, photophobia, gritty/scratchy/sandy feelings in eye and vision quality were assessed by each subject for both the study and non-study fellow eyes at baseline and post-operative visits. The changes in symptoms were evaluated and there were no statistically significant worsening symptoms or quality of vision.

The primary safety criterion of rate of adverse events was met, as well as other secondary variables of safety and surgical experience. The results of this study indicated that the iFS Laser System can safely perform intrastromal arcuate incisions in the cornea.

CONCLUSION:

The laboratory and animal study data support that the arcuate incisions can be executed by the iFS Laser System as prescribed by the physician. These data demonstrate the iFS Laser System is safe and effective when used in conjunction with the directions for use and inherent warnings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Medical Optics, Inc.
c/o Ms. Kesley E. Gallagher
Project Manager, Refractive Regulatory Affairs
1700 E. St. Andrew Place
Santa Ana, CA 92705

MAR - 8 2012

Re: K113151
Trade/Device Name: iFS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX, HNO
Dated: February 15, 2012
Received: February 17, 2012

Dear Ms. Gallagher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CDRH INDICATIONS FOR USE

510(k) Number (if known): K113151

Device Name(s): iFS Laser System

Indications for Use:

The iFS Laser System is an ophthalmic surgical laser indicated for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty
- In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal

Prescription Use: X **AND/OR** **Over-the-Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113151